

REMARKS

Applicants wish to thank Examiner Bland for the attention accorded to the instant application, and respectfully requests reconsideration of the application as amended.

Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38 and 40-54 are pending. Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38 and 40-51 have been examined on the merits. Previously submitted Claims 52-54 have been withdrawn in the Official Action. Applicants reserve the right to re-file the subject matter of Claims 52-54 in a continuing application.

The Office Action rejects Claims 1, 5-13, 16-19, 24, 27-28, 32-35, 38, 40-44 and 47-51 under 35 U.S.C. §103(a) as allegedly unpatentable over Canadian Patent Application 2,340,103 to Stahl et al. (Stahl) in view of Am. J. Clin. Nutr 2000, 72: 1503-9 (Jie), International Patent WO 02/39832 to Brokx et al (Brokx), Livesey et al. (European Journal of Clinical Nutrition (1993) 47, 419-430) (Livesey), and “Medical Nutrition Therapy for Lower Gastrointestinal Tract Disorders,” Krause’s Food, Nutrition and Diet Therapy (ed. 10), 2000, pages 667-694 by Beyer (Beyer).

The Office Action rejects Claims 1, 5-13, 16-19, 24, 27, 28, 30, 32-35, 38 and 40-51 under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and U.S. Patent 5,443,826 to Borody (Borody).

The Office Action rejects Claims 26 and 28 under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey, Beyer and in view of U.S. Patent 5,601,863 to Borden et al. (Borden). The Office Action rejects Claims 26 and 28 under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden.

Claims 1, 38, 47, 48, and 49 have been amended to remove various claim recitations. Claim 38 has been amended to recite that the polydextrose is administered in an amount of 1 to 100 g/day and the ratio between polydextrose and a polyol is 1:10 to 10:1. Support for this amendment can be found throughout the specification and particularly in the third full paragraph on page 16. Claims 1, 38, 45, 47, 48, 55 and 56 have been amended to recite polydextrose being a slowly fermented carbohydrate. Support for these amendments can be found throughout the application, such as in the fourth full paragraph of page 10.

Applicants respectfully submit new claims 55 and 56 for examination. Claim 55 is directed to, *inter alia*, a method for preventing accumulation of lactic acid in the colon of a mammal treated with antibiotics, comprising administering to said mammal an amount of 1 to 100 g/day of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose in combination with at least one polyol in a ratio of 1:10 to 10:1. Claim 56 is directed to, *inter alia*, a method for preventing accumulation of lactic acid in the colon of a mammal with a short intestine, comprising administering to said mammal an amount of 1 to 100 g/day of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose in combination with at least one polyol in a ratio of 1:10 to 10:1. No new matter has been added by way of the aforementioned Claim additions. For example, Applicants direct the Examiner's attention to the third full paragraph on page 16, the fourth full paragraph of page 10 and previously filed Claims 1, 38, 45, 47 and 48. Applicants submit that the identified sections are presented only for the Examiner's convenience and is not intended to be an exhaustive list of support.

In view of the following remarks, Applicants request further examination and reconsideration of the present patent application.

Rejections under 35 U.S.C. §103

Claims 1, 5-13, 16-19, 24, 27-28, 32-35, 38, 40-44 and 47-51 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey, and Beyer.

Independent Claims 1, 38, 47 and 48 have been amended to recite administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon.

The combination of Stahl, Jie, Brokx, Livesey and Beyer does not teach or suggest the claimed invention.

Stahl discloses the incorporation of a mixture of two different carbohydrates in dietetic nutritions and pharmaceuticals to stimulate health-promoting microorganisms present in the natural flora of the large intestine. See page 3 lines 15-21 of Stahl. Stahl further discloses that in a preferred embodiment, a mixture of different carbohydrates will promote lactic acid bacteria to a surprising degree in the intestine. See page 7 line 27 to page 8 line 5 of Stahl. Stahl does not teach or suggest the use of polydextrose and lactitol.

Stahl does not disclose the use of a polyol and does not disclose polydextrose as a possible carbohydrate. A person skilled in the art would not have selected polydextrose as a suitable carbohydrate based on the disclosure of Stahl, and would not have selected the combination of polydextrose and a polyol based on Stahl. There is no disclosure, teaching or suggestion in Stahl for this combination. In contrast, polydextrose and a polyol have properties that are clearly different from the prebiotic carbohydrates mentioned, exemplified and preferred in Stahl.

Stahl discloses and prefers the use of inulin, which is distinct from polydextrose as exemplified in Examples 1 and 2 of the present application. Inulin does not have the slow and sustained release properties of polydextrose, as recited in Claims 1, 38, 47, 48 and all claims

depending therefrom of the present application. Also, inulin is quickly fermented and has no sustained release properties, so it creates an increase of lactobacilli at the upper end of the colon, increasing the risk of acidosis. Based on Stahl, a person of ordinary skill in the art would not choose polydextrose from the large range of all possible carbohydrates. A compound is not obvious where the prior art does not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives. *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008).

Stahl provides no apparent reason for selecting polydextrose from among the large number of unpredictable carbohydrates disclosed in Stahl and the cited art. Not all prebiotic carbohydrates listed in Stahl have the slow release and therapeutic properties of polydextrose, with many having unpredictable results on the reduction of lactic acid accumulation. Therefore, polydextrose is not an obvious compound to use based on the primary reference Stahl.

Further, page 8 of Stahl refers to the article “Dietary Modulation of the Human Colonic Microbiota: Introducing the Concept of Prebiotics” J. Nutr. 1995 by Gibson et al. (Gibson). A copy of this reference is enclosed for Examiner Bland’s convenience. Stahl refers to Gibson for the selection of prebiotically active carbohydrates. Gibson also specifically used inulin, a fructo-oligosaccharide, as a preferred prebiotic. Table 1 on page 1406 of Gibson indicates that various non-starch polysaccharides (polydextrose is a non-starch polysaccharide) are not prebiotic in nature while fructo-oligosaccharides are. Based on Gibson, Stahl teaches against the selection of the non-starch polysaccharide, polydextrose as a possible prebiotic carbohydrate.

Thus, without the Stahl reference, the rejection under 35 U.S.C. §103(a) cannot stand. Withdrawal of the rejection based on the foregoing remarks alone is respectfully requested.

Livesey discloses administration of a confection containing polydextrose and lactitol to a range of people of different ages. See page 420 of Livesey. Livesey discloses this administration in an effort to study the hydrogen production of from different alternative carbohydrate is similar or not. See Abstract of Livesey. Livesey does not disclose the treating of any group other than individuals of varying ages.

Livesey discloses that when humans consume polydextrose and lactitol, the hydrogen breath test shows an increase in hydrogen in excess of what is expected. In the Livesey disclosure, the increased hydrogen production of polydextrose and lactitol shows that some unspecified carbohydrate is fermented in the colon and that the fermentation rate is increased, thus emitting more hydrogen. There is no indication in Livesey that accumulation of lactic acid can be prevented and that certain disorders can be treated with the combination of polydextrose and lactitol as recited in Claims 1, 38, 47 and 48, and all claims depending therefrom of the present application.

Jie discloses a drop in pH levels as polydextrose intake increases, which would aggravate a condition where a low pH level caused by lactic acid accumulation is causing an imbalance in colon fermentation. See page 1507, Table 4 of Jie. Further, Jie discloses the use of polydextrose alone in water. Jie does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon as recited in independent Claims 1, 38, 47 and 48, and all claims depending therefrom.

Brokx discloses the administration of lactitol contained in a food product to increase the amount of bifidobacteria in the gut of a person. See page 2 lines 7-21 of Brokx. Brokx does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid

accumulation in the colon as recited in independent Claims 1, 38, 47 and 48, and all claims depending therefrom.

Beyer discloses that prebiotics or fermentable sugars may be used to treat various diseases including diarrhea, lactose intolerance, inflammatory bowel disease and pouchitis. Assuming Beyer does state that fermentable sugars can be used to treat diarrhea and other diseases, neither lactitol nor polydextrose are fermentable sugars. Lactitol is not a sugar at all and polydextrose is not fermentable, and is considered by those skilled in the art to be generally non-fermentable.

The portions of Beyer provided describe a large number of different ways in which disorders in the gastrointestinal tract can be treated. The combination of polydextrose with lactitol is not disclosed. Further, Beyer states that “Sugar alcohols, lactose, fructose and large amounts of sucrose may worsen osmotic diarrheas and may have to be limited.” See page 671, right hand column, third full paragraph of Beyer. This disclosure would motivate a person of ordinary skill in the art to look away from the Beyer disclosure.

Further, Beyer offers more disclosures that teach against the present invention, including that to treat inflammatory bowel diseases, “a diet that limits whole fibrous foods might be used...” See page 681-686 of Beyer. Polydextrose is a fibrous food, Beyer discloses that it should be limited. Beyer also suggests that “the use of fermentable fibers” is among the therapeutic strategies being considered. See page 685, left hand column of Beyer. Polydextrose is a substantially non-fermentable fiber. Thus, Beyer does not suggest or teach polydextrose for inflammation. Beyer mentions pouchitis in the right hand column of page 692 but suggests that antibiotics are the primary form of therapy.

Further, even if Beyer did disclose the use of prebiotics to treat diseases including diarrhea, lactose intolerance, inflammatory bowel disease and pouchitis, which it does not, there

is no disclosure of administering at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon as recited in independent Claims 1, 38, 47 and 48, and all claims depending therefrom.

Even though the Office Action has cited references which disclose the use of lactitol, there is absolutely no reason to combine any of them with Stahl. Stahl does not mention polydextrose or lactitol as a suitable substance to use and relies on the Gibson article which teaches against the use of polydextrose as a prebiotic. A person of ordinary skill in the art would have no reason to look to any of the cited references because none of the cited references disclose a mixture of two prebiotic carbohydrates. Would a person of ordinary skill in the art, relying on the Stahl disclosure which discloses the use of two prebiotic carbohydrates, look to a reference that disclosed the use of one carbohydrate and one sugar alcohol?

Based on the deficiencies of the above references, there is no teaching, suggestion or motivation for one of ordinary skill in the art to practice or use the claimed method of reducing lactic acid accumulation in the colon of a subject from the groups recited in Claims 1, 38, 47 and 48, and all claims depending therefrom. Thus, the rejection of Claims 1, 5-13, 16-19, 24, 27-28, 32-35, 38, 40-44 and 47-51 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 24, 27-28, 32-35, 38, 40-44 and 47-51 is earnestly solicited.

Claims 1, 5-13, 16-19, 24, 27, 28, 30, 32-35, 38 and 40-51 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody.

The deficiencies of Stahl, Jie, Brokx and Livesey are discussed above. Borody does not cure those deficiencies.

Borody discloses the treatment of various diseases related to the presence of abnormal microflora in the gastrointestinal tract. See column 1 lines 65-69 of Borody. Borody further discloses the removal of a person's enteric microflora and the substitution of the removed microflora with an amount of fresh or dried feces from another human donor. See column 3 lines 57-68 and Claim 1 of Borody. Removing bacteria by lavage and restoring the microflora by eating live bacteria is a totally different disclosure from eating a combination which does not contain microbes. Polydextrose and polyol are both chemicals free from live bacteria. Thus Borody does not give any suggestion or motivation to a person of ordinary skill in the art to practice the method of the claimed invention.

At the least, Borody does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon as recited in independent Claims 1, 38, 45, 47 and 48, and all claims depending therefrom.

Therefore, the combination of Stahl in view of Jie, Brokx, Livesey and Borody would not disclose, teach or suggest this feature.

Thus, the rejection of Claims 1, 5-13, 16-19, 24, 27, 28, 30, 32-35, 38 and 40-51 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 1, 5-13, 16-19, 24, 27, 28, 30, 32-35, 38 and 40-51 is earnestly solicited.

Claims 26 and 28 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey, Beyer and in view of Borden.

The deficiencies of Stahl, Jie, Brokx, Livesey and Beyer are discussed above. Borden does not cure these deficiencies.

Borden teaches polymerization of polydextrose by exposing the polydextrose to hydrogen gas in the presence of a hydrogenation catalyst or a hydride donor. See column 1 line 59 to column 2 line 2. Borden does not teach or suggest a method of treatment for any subject. Further, Borden does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claims 26 and 28 depend. Therefore, the combination of Stahl, Jie, Brokx, Livesey and Beyer with Borden would not disclose this feature.

Thus, the rejection of Claims 26 and 28 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection and allowance of Claims 26 and 28 is earnestly solicited.

Claims 26 and 28 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden.

The deficiencies of Stahl, Jie, Brokx, Livesey and Borody are discussed above. Specifically, the combination of Stahl, Jie, Brokx, Livesey and Borody does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which Claims 26 and 28 depend. Borden does not cure these deficiencies.

Borden teaches polymerization of polydextrose by exposing the polydextrose to hydrogen gas in the presence of a hydrogenation catalyst or a hydride donor. See column 1 line 59 to column 2 line 2. Borden does not teach or suggest a method of treatment for any subject. Further, Borden does not disclose administration of at least one polyol and an amount of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose provided in an amount effective to reduce lactic acid accumulation in the colon, as recited in Claim 1, from which

Claims 26 and 28 depend. Therefore, the combination of Stahl in view of Jie, Brokx, Livesey and Borody and further in view of Borden does not disclose this feature.

Thus, the rejection of Claims 26 and 28 under 35 U.S.C. §103(a) is overcome.

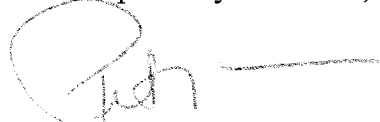
Withdrawal of the rejection and allowance of Claims 26 and 28 is earnestly solicited.

Further, new Claims 55 and 56 are patentable over the cited references. These new claims are patentable because none of the cited references, alone, or in any proper combination, disclose, teach or suggest a method comprising administering to a mammal an amount of 1 to 100 g/day of slowly fermented carbohydrate, wherein said carbohydrate is polydextrose in combination with at least one polyol in a ratio of 1:10 to 10:1. Allowance of new Claims 55 and 56 is earnestly solicited.

Applicants believe that the foregoing remarks and amendments submitted herein provide a complete response to the Office Action, and the present case is in condition for allowance. Therefore, in view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all rejections, and allowance of all pending claims in due course.

If the Examiner believes that a telephone conference with the Applicants attorneys would be advantageous to the disposition of this case, the Examiner is requested to contact the undersigned, at the number provided below.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser, P.C.
400 Garden City Plaza-Suite 300
Garden City, New York 11530
(516) 742-4343
PIB/DRB:vc
Enc.(Glenn Publication)